

REMARKS

Claims 90-96 and 113-125 were pending in the application. In the Office Action mailed March 25, 2008, claims 90-96 and 113-125 are rejected. In the instant Amendment, claims 90, 93, 118 and 120-121 have been amended, and claims 126-132 have been added. Upon entry of the instant Amendment, claims 90-96 and 113-132 will be pending in the application.

Claim 90 has been amended to recite that the gastric retention vehicle composition provides a homogenous solid matrix. The recitation, as amended, is therefore a non-narrowing amendment of the claim as originally filed.

Claim 93 has been amended to recite that the first and second reservoirs are embedded in said gastric retention vehicle composition. Support for the amendment is found in the specification at, e.g., page 11, lines 2-3; and page 20, lines 18-20.

Claim 118 has been amended to delete the phrase "a polymeric coating substance."

Claims 120-121 have been amended to be dependent on claim 119.

Support for new claims 126-132 is found in the specification at, e.g., page 13, line 26 through page 14, line 8.

No new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

THE FILING DATE OF THE LAST RESPONSE

In the Office Action Summary, the Examiner indicates that the response to the previous office action mailed June 4, 2007 was filed on December 7, 2007. In the Detailed Action, the Examiner acknowledges receipt of the response filed on September 26, 2006. Applicant respectfully submits that the response to the office action mailed June 4, 2007 and accompanying filing papers were deposited with the U.S. Postal Service with sufficient postage as first class mail on December 4, 2007. A certificate stating the date of deposit, *i.e.*, December 4, 2007, was included on each documents (copies of these documents are available at PAIR). Pursuant to 37 C.F.R. 1.8(1), a filing date of December 4, 2007 should be

accorded. Applicants respectfully request that the correct filing date be used in connection with any communications in the present application.

APPLICANTS' INTERVIEW SUMMARY

Applicants wish to thank Examiner Fubara for the courtesy extended to Applicants' representatives Messrs. David Wallace (in person) and Weining Wang (via telephone) for the interview conducted on July 22, 2008 ("the interview"). During the interview, the 103 rejection was discussed. Applicants' representatives explained to Examiner Fubara that the presently claimed composition comprises recited amounts of superdisintegrant, hydrogel, and tannic acid, wherein, upon contact with gastric fluid the composition expands to a sufficient degree such that the dosage form is retained in the stomach. Applicants' representatives also explained that neither Burnside nor Swanson teaches or suggests enhancing the expansion and strength of a matrix such that it is retained in the stomach. The Examiner suggested that Applicant provide data showing unexpected results of the invention. Although Applicants believe that the Office has not established *prima facie* obviousness, Applicants will consider submitting data further supporting the patentability of the claimed invention.

During the interview, the 112, first paragraph, rejection was also discussed. Applicants' representatives explained that gastric fluid as used in the present application refers to fluid of the stomach. The Examiner indicated that the rejection due to the recitation "into the stomach" would be withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 112

Claims 90-96 and 113-125 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter for the recitation of "into the stomach." As discussed above in the interview summary, the Examiner has indicated that the rejection will be withdrawn.

Claims 119-121 stand rejected under 35 U.S.C. § 112, second paragraph, for the recitation of "hydrophobic and hydrophilic." The Examiner states that there is insufficient antecedent basis for this limitation. Applicants respectfully point out that claim 119 recite that the coating "comprises polymethacrylate, or a mixture of hydrophilic and hydrophobic film forming agents" (emphasis added). The recitation of "hydrophobic and hydrophilic" appears in this claim for the first time, and therefore does not require antecedent basis. Applicants have amended claims 120-121 to be dependent on claim 119. The rejection

should therefore be withdrawn.

Claim 118 stands rejected under 35 U.S.C. § 112, second paragraph, for reciting the phrase “a polymeric coating substance.” Applicants have deleted the phrase from the claim. The rejection is therefore obviated.

THE REJECTIONS UNDER 35 U.S.C. § 103

Claims 90-96, 113-114 and 115-125 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. patent No. 6,322,819 (“Burnside”) in view of U.S. patent No. 4,326,525 (“Swanson”). In particular, the Examiner asserts that Burnside discloses a multiple pulsed dose delivery system containing methylphenidate with a disintegration agent and a hydrogel and Swanson discloses a dosage form containing methylphenidate and tannic acid. According to the Examiner, the combination of the delivery system of Burnside with the tannic acid disclosed in Swanson results in the dosage form recited in the claims. Applicants respectfully traverse.

The claims recite a pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising a gastric retention vehicle composition comprising about 10 wt-% to about 75 wt-% superdisintegrant, about 2 wt-% to about 12 wt-% tannic acid, and about 20 wt-% to about 70 wt-% of a hydrogel, wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained in the stomach and wherein the methylphenidate is released in at least two portions. As Applicants have shown, the amounts of hydrogel, superdisintegrant, and tannic acid affect the expansion and strength of the dosage form (see, e.g., Examples 1, 2 and 3 of the present application). The presently claimed compositions, by using the claimed amounts of hydrogel, superdisintegrant, and tannic acid, achieve the goal of gastric retention.

Burnside teaches a multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising an immediate-release component and an enteric delayed-release component wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating (*see, e.g.*, Burnside, Abstract). Burnside teaches that its drug delivery

system can contain a binder and a disintegrant. However, Burnside does not teach including tannic acid in its drug delivery system. Burnside does not teach or suggest a formulation for gastric retention. Nor does Burnside teach or suggest the effects of the amounts of hydrogel and superdisintegrant on the expansion and strength of the formulation.

Swanson teaches an osmotic device comprising an agent and a buffer, which interact in the device to produce an agent with controlled solubility in the fluid (*see, e.g.*, Swanson at col. 2, lines 40-49). The buffer can be, *inter alia*, an acidic compound that is capable in an aqueous solution of reacting with a counter basic agent to produce an aqueous soluble agent salt within the device for dispensing the agent salt at a substantially zero order rate from the device over time (*see, e.g.*, Swanson at col. 7, lines 21-29). Swanson teaches that the preferred acidic compounds are fumaric acid, succinic acid, tartaric acid, citric acid, maleic acid, benzoic acid, ascorbic acid, oxalic acid, nicotinic acid, lactic acid, phthalic acids, pimamic acid, pimelic acid, tannic acid, urea hydrochloride, glycine, mandelic acid, glycolic acid, sodium monobasic phosphate, potassium bisulfite, potassium monobasic phosphate, and the like (*see, e.g.*, Swanson at col. 7, lines 39-47). Thus, Swanson teaches the inclusion of an acid in its device for reacting with a base to produce a salt, not for enhancing the expansion and strength of a matrix. Swanson teaches as preferred acids a long list of over twenty acids, with tannic acid as but one of the list.

The Examiner has not provided a reason why a person skilled in the art would have modified Burnside by including tannic acid in its formulation. As discussed above, Burnside does not teach a formulation for gastric retention. Nor does Burnside teach or suggest the effects of the amounts of hydrogel, superdisintegrant, and tannic acid on the expansion and strength of the formulation. A person skilled in the art would not have been led by Burnside to a formulation for gastric retention, much less to a formulation that includes tannic acid in the recited amount so as to have the expansion and strength suitable for gastric retention.

Swanson does not supply what is missing in Burnside. Swanson is not concerned with a gastric retention formulation. Swanson teaches the inclusion of an acid in its device for reacting with a base to produce a salt. Since there is no such a need for Burnside, a person skilled in the art would not have been led by Swanson to modify Burnside by adding an acid to its formulation. In addition, Swanson teaches a long list of over twenty preferred acids that can be used for its purpose (*see, e.g.*, Swanson at col. 7, lines 39-47). Swanson

does not teach or suggest that tannic acid is of any more preference over any of the other acids. The Examiner has not provided a reason why a person skilled in the art would have picked tannic acid over the other acids. Furthermore, the Examiner has not provided a reason why a person skilled in the art would have included the recited amount of tannic acid in a formulation.

Given that Burnside and Swanson each is not concerned with a composition for gastric retention, the Examiner has not provided a reason why a person skilled in the art, seeking a formulation for gastric retention and without knowledge of the claimed invention, would have picked these disclosures and combined them in such a way as to arrive at the claimed compositions. Nor has the Examiner provided evidence that a person skilled in the art, without knowledge of the claimed invention, would have expected to be able to successfully achieve gastric retention by simply combining the two. In this regard, it is noted that the amounts of hydrogel, superdisintegrant, and tannic acid affect the expansion and strength of the formulation, while neither Burnside nor Swanson teaches selecting the amounts of these substances so as to achieve desired expansion and strength of the formulation.

Claims 90, 93, 116 and 117 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Burnside in view of Swanson in further view of U.S. patent no. 5,847,090 (“Baker”). The Examiner indicates that claims 90 and 93 are rejected as being obvious over Burnside in view of Swanson, while Baker is cited for its teaching that methylphenidate can be used to treat hyperactivity.

Baker teaches d-threo-methylphenidate (dtmp) as a suitable substance for use in a sustained-release formulation (*see*, Baker, col. 1, lines 47-54). Baker is not concerned with gastric retention. Baker does not teach inclusion of hydrogel, superdisintegrant, and tannic acid in its formulation.

Therefore, Baker does not supply what is missing in Burnside and Swanson with respect to claims 90 and 93. Claims 116 and 117 are method claims dependent on claims 90 and 93, respectively. Since the base claims 90 and 93 are not obvious over Burnside, Swanson and Baker, claims 116 and 117 are also not obvious.

For all of these reasons, Applicants respectfully submit that claims 90-96, 113-114

and 115-125 are not obvious over Burnside and Swanson, and claims 90, 93 and 116-117 are not obvious over Burnside, Swanson and Baker. The rejections of these claims under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. The Commissioner is hereby authorized to charge the fee for a one-month extension of time, and any other fees required for consideration of this paper, to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully Submitted,

KENYON & KENYON

Dated: September 24, 2008

By: /W. David Wallace/
W. David Wallace
Reg. No. 42,210

KENYON & KENYON LLP
One Broadway
New York, NY 10004-1007
Telephone: 212-425-7200
Facsimile: 212-425-5288
Customer Number 26646